

PATENTABILITY UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Applicants note that *Lactobacillus helveticus* CM-4 FERM BP-6060 was deposited under the terms of the Budapest Treaty on August 15, 1997. *Lactobacillus helveticus* CM-4 FERM BP-6060 was deposited with the National Institute of Bioscience and Human-Technology Agency of Industrial Science and Technology in Japan, which is an International Depository Authority under the Budapest Treaty. Applicants enclose herewith a copy of the corresponding Deposit Receipt. Applicants believe that the deposit of *Lactobacillus helveticus* CM-4 FERM BP-6060 with an International Depository under the Budapest Treaty obviates each of the Examiner's present bases for rejection; submit that claims 1, 6, 7, 9, 14, and 15 are allowable under 35 U.S.C. §112, first paragraph; and respectfully request that the Examiner issue a Notice to that effect.

PATENTABILITY UNDER 35 U.S.C. §102

Claims 1-6 and 9-14 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by EP Patent No. 583074 ("the '074 patent"), JP Patent No. 2782153 ("the '153 patent"), or US Patent No. 5,449,661 ("the '661 patent"). The Examiner alleges that these references teach (1) that *Lactobacillus helveticus* is mixed with skim milk to produce fermented milk, (2) that yeast can be added to the mixture as well, (3) that the viscosity of the milk is inherent to the milk, and (4) that "to mix" only requires combining into one mass.

As a preliminary matter, Applicants note that, by the present Amendment an Response, claims 10-14 are now cancelled thereby obviating the present bases for rejection of those claims. Claims 1, 5, 6 and 9 are amended as set forth above. Each of claims 2-6 and 9 depend from and contain each of the limitations of claim 1. Because none of the cited references contain each of the elements of claim 1, it necessarily follows that none of the cited references contain each of the elements of claims 2-6 and 9. Thus, the novelty of claims 2-6 and 9 necessarily flows from the novelty of claim 1.

Nonetheless, Applicants respectfully traverse the stated grounds for rejection under 35 U.S.C. §102(b) and submit that neither the '074 patent, the '153 patent, nor the '661 patent disclose each element of instant claims. Therefore, none of these references anticipate any of instant claims 1-6 and 9.

Claim 1, as presently amended, is directed to a method for producing fermented milk containing angiotensin converting enzyme inhibitory peptide. The method of claim 1 comprises the steps of (1) preparing a mixture of lactic acid bacteria and a starting material containing milk and (2) fermenting the mixture while stirring at least during the period when the pH of the mixture is lowered from 5 to 4, 6, so that curd pieces and whey are generated, whereby fermented milk containing said curd pieces and said whey containing the angiotensin converting enzyme inhibitory peptide is produced. As Applicants disclose in the specification, at pH 5, soft curds start to be generated in the mixture, and at pH 4.6, casein reaches its isoelectric point. By stirring the mixture at least over this pH range, the curd (precipitate) being formed is broken up into smaller pieces as it is formed, which further facilitates later separation of whey (supernatant) from the fermented milk.

Claims 1-4, 6, 8-12, 14 and 16 stand rejected under 35 §102(b) as allegedly anticipated by Yamamoto *et al.* '796 ("the '796 patent") or Yamamoto *et al.* '111 ("the '111 patent"). The Examiner alleges that these references teach that *Lactobacillus helveticus* is mixed with skim milk to produce fermented milk. According to the Examiner, the fermented milk inherently contains the peptide since the same starting materials are used and since the process is the same. The Examiner further alleges that the viscosity of the milk is inherent to the milk. Finally, the Examiner asserts that "to mix" only requires combining into one mass.

but alleges that '796 patent or the '111 patent overcome that deficiency by teaching the recovery of whey from fermented milk.

Claims 1-16 also stand rejected under 35 U.S.C. §103(a) as obvious over the '796 patent or the '111 patent in view of either the '074 patent, the '153 patent, or the '661 patent. The Examiner concedes that the cited references do not teach using the specific strain *Lactobacillus helveticus* CM4 FERM BP-6060. The Examiner alleges, however, that it would have been obvious to use such a strain since such strains are well known in the art. The Examiner alleges that the strain disclosed in the cited references would be expected to produce the same enzyme inhibitor as that produced by *Lactobacillus helveticus* CM4 FERM BP-6060. The Examiner also concedes that neither the '796 patent nor the '111 patent teach using yeasts along with bacteria to produce fermented milk, but alleges that it would have been obvious to use yeasts along with the claimed bacteria to produce fermented milk in view of the '074 patent, the '153 patent, or the '661 patent.

As a preliminary matter, Applicants note that, by the present Amendment and Response, claims 10-16 are cancelled thereby obviating the present basis for rejection of these claims. Claims 1, 5, 6, 8, and 9 are amended as set forth above. Each of claims 2-9 depend from and contain each of the limitations of claim 1. Because the cited references, viewed as a whole, fail to teach or suggest each of the elements of claim 1, it necessarily follows that none of the cited references teach or suggest each of the elements of claims 2-9. Thus, the nonobviousness of claims 2-9 necessarily flows from the nonobviousness of claim 1.

Nonetheless, Applicants respectfully traverse the stated grounds for rejection of instant claims 1-9. More specifically, none of these references teach fermentation while stirring at least over the particular pH range as in the present invention. Furthermore, these references are silent about stirring either (a) to form smaller curd pieces or (b) to facilitate later separation of whey from the fermented milk.

Accordingly, Applicants respectfully submit that the instant claims distinguish patentably (1) over the '074 patent, the '153 patent, or the '661 patent in view of either the '796 patent or the '111 patent or (2) over the '796 patent or the '111 patent in view of either the '074 patent, the '153 patent, or the '661 patent. Applicants therefore submit that the instant claims

CONCLUSION

Respectfully submitted,

Page 11 of 11

国際様式

INTERNATIONAL FORM



特許手続上の微生物の寄託の国際的承認
に關するブダペスト条約

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF
MICROORGANISMS FOR THE PURPOSES OF
PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL
DEPOSIT

下記国際寄託当局によって規則 7. 1 に従い
発行される。

issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified at the bottom of this
page.

原寄託についての受託証

氏名 (名称) カルビス食品工業株式会社
代表取締役 小林 公生 股
寄託者 あて名 〒 150
東京都渋谷区恵比寿西2-20-3

1. 微生物の表示	
(寄託者が付した識別のための表示) ラクトバチルス・ヘルベチカス CM-4 (Lactobacillus Helveticus CM-4)	(受託番号) FERM BP- 6060
2. 科学的性質及び分類学上の位置	
1欄の微生物には、次の事項を記載した文書が添付されていた。 <input checked="" type="checkbox"/> 科学的性質 <input checked="" type="checkbox"/> 分類学上の位置	
3. 受領及び受託	
本国際寄託当局は、平成 9 年 8 月 15 日 (原寄託日) に受領した1欄の微生物を受託する。	
4. 移管請求の受領	
本国際寄託当局は、 年 月 日 (原寄託日) に1欄の微生物を受領した。 そして、 年 月 日に原寄託よりブダペスト条約に基づく寄託への移管請求を受領した。	
5. 国際寄託当局	
<p>通商産業省工業技術院生命工学工業技術研究所</p> <p>名称: National Institute of Bioscience and Human-Technology Agency for Industrial Science and Technology</p> <p>所長 大石 道雄 Michio Ohtani, DIRECTOR GENERAL.</p> <p>あて名: 日本国茨城県つくば市東1丁目1番3号 (郵便番号305) 1-3, Higashi-Tsukuba-shi Ibaraki-ken 305, JAPAN</p>	
平成 9 年 (1997) 8月15日	



INTERNATIONAL FORM

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page

To Depositor: Name - The Calpis Food Industry Co., Ltd.
Kimio KOBAYASHI, Director-Representative
Address - 20-3, Ebisu-Nishi 2-chome, Shibuya-ku,
Tokyo 150

1. Name of Microorganisms:

(Name for Identification given by Depositor)
Lactobacillus helveticus CM-4

(Accession Number)
PERM BP- 6060

2. Scientific Description and Taxonomic Designation:

A written statement describing the following information was appended to the microorganism of Section I.

Scientific Description - Yes
Taxonomic Designation - Yes

3. Acknowledgement and Receipt:

The present International Depositary Authority has accepted the deposit of the microorganism in Section I acknowledged on August 15, 1997 (the date of an original deposit).

4. Acknowledgement of Petition for Conversion:

5. International Depositary Authority:

Name - National Institute of Bioscience and Human-Technology
Agency of Industrial Science and Technology,
Ministry of International Trade and Industry
Michio OISHI, Ph. D., Director General
Address - 1-3, Higashi 1 chome, Tsukuba-shi, Ibaraki-ken,
305 Japan.

(SEAL)

Dated: August 15, 1997